Testimony Before the
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
Sick Crime: Counterfeit Drugs in the United States
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Mr. Chairman and Members of the Subcommittee:

I am honored to be here today and discuss with you the growing concern with counterfeit drugs and the threat these products pose to the integrity and validity of the Nation's medication distribution system.

The National Association of Boards of Pharmacy (NABP), which I represent, was founded in 1904. Our members are the pharmacy regulatory and licensing jurisdictions in the United States, District of Columbia, Guam, Puerto Rico, and the Virgin Islands, eight provinces of Canada, three Australian States, New Zealand, and South Africa. Our purpose is to serve as the independent, international, and impartial Association that assists states and provinces in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.
Testimony

THE PROBLEM OF COUNTERFEIT DRUGS

Reports from the Food and Drug Administration (FDA) and World Health Organization (WHO) estimate that the incidence of counterfeit drugs is a growing concern. Although the US medication distribution system remains safe and secure, the challenges federal and state regulators face to maintain its safety and security are significant. Further complicating this public health crisis are the illegal importation of drugs, continued erosion of state and national borders, and a complete disregard for US federal and state laws by those entities engaged in the production and distribution of counterfeit drugs.
For state boards of pharmacy, constitutionally charged with regulating an ever changing and more complex practice of pharmacy with diminishing resources, the situation is at times critical. It is a situation exacerbated by the reckless actions of local and state public officials and governments who ignore public health and safety in order to promote the illegal importation of drugs. Maintaining the security and integrity of the US medication distribution system will not be an easy task. More importantly, if the US medication distribution system is compromised by the influx of illegally imported products then state and federal regulators will be powerless to protect US consumers from the dire situation of a medication distribution system that cannot provide legitimate medications to its patients. If this situation occurs, no one will be protected, no one will be safe.

The estimates of the prevalence of counterfeit drugs released from the WHO and FDA vary from country to country but sound a similar concern. The concern is quite alarming particularly when the estimates of counterfeit drugs range as high as 40 – 60% for some African, Latin, and South East Asian countries. "The FDA believes that counterfeiting is not widespread within the system of manufacturing and distributing pharmaceuticals legally in the United States, as a result of an extensive system of federal and state regulatory oversight and steps to prevent counterfeiting undertaken by drug manufacturers, distributors, and pharmacies. However, the agency has recently seen an increase in counterfeiting activities as well as increased sophistication in the methods used to introduce finished dosage form counterfeits into the otherwise legitimate U.S. drug distribution system. FDA counterfeit drug investigations have increased to over 20 per year

since 2000, after averaging only 5 per year through the late 1990's. Increasingly, these investigations have involved well-organized criminal operations that seek to introduce finished drug products that may closely resemble legitimate drugs yet may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated. Thus, drug counterfeiting poses real public health and safety concerns today, and may pose an even greater threat in the future if we fail to take preventative measures now. As counterfeiters continue to seek out new technologies to make deceptive products and introduce them into legitimate commerce, our systems for protecting patients must respond effectively."[1]

In a presentation to the Drug Information Association in Ottawa Canada in November of 2003, then Commissioner McClellan noted that, "we're facing more serious international threats from criminals and profiteers who are trying to make a fast buck by going where the money is – which increasingly means prescription drugs and other medical products. We're seeing international counterfeit drug operations that are increasingly sophisticated and criminal networks that are better organized than ever before."[2] Information contained on the FDA web site illustrates the complexity of this issue and the ability of counterfeiters to duplicate products and product packaging. For the unknowing and unsuspecting patient, detecting counterfeit drugs is for all practical purposes impossible.

NABP MONITORING AND FINDINGS

Internet Drug Buys

NABP and the state and federal regulatory communities continue to focus on the public health hazards of counterfeit and adulterated drugs entering the US distribution system. These medications often reach US consumers when a patient orders the drug from a Web site, sometimes one alleging to be a US or Canadian site or allegedly connected with the US or Canada, in order to increase consumer confidence. Since 2004, NABP has participated in several high profile Internet drug buy projects in order to illustrate the ready access consumers have to medications that should only be prescribed and monitored by a physician and the perils they face when ordering such products online.

Controlled Substances and Isotretinoin

In December 2003 and January 2004, NABP in conjunction with a team from Dateline NBC purchased eight (8) different drugs from five (5) suspicious Internet pharmacy sites to demonstrate the ease with which dangerous drugs can be purchased without a prescription. Disturbingly, none of the drugs NABP received appeared to be shipped from the country in which the pharmacy Web site was registered and all of the drugs were labeled in a foreign language. The site offering Roaccutane® shipped the drug without proof of pregnancy testing or other evidence to determine if the therapy was appropriate, as is required by the US Food and

[1] Food and Drug Administration, COMBATING COUNTERFEIT DRUGS: A Report of the Food and Drug Administration, February 2004.

[2] McClellan, Mark B. Speech before the Drug Information Association. November 18, 2003, Ottawa, Canada.

Drug Administration (FDA) and legitimate medical practice.

After receiving the drugs, NABP sent the following items to the United States Pharmacopeia (USP) for identification testing:

- "Valium® 10 Roche, Tabletten Wirkstoff: Diazepam" (10 mg, #90 tablets)
- "Alprazolam Normon 1 mg Comprimidos EFG" (#30)
- "Codeisan" (30 mg, #40 tablets)
- "Roaccutane® isotretinoin 10 mg" (#30 capsules)
- "Testabol Depot® Testosterone Cypionate 10 ml For Intramuscular Injection" (4 x 10 ml vials, 200 mg/ml)

USP assays found that four out of the five drugs NABP submitted for testing contained the correct and appropriate amount of the active ingredient; however, two vials of the testosterone failed the USP's specification for potency (they only contained half of the dosage) and viscosity. These results indicated that one in five patients could receive drugs that are not full strength. It is important to note that USP performed limited testing; several other tests that could uncover potential dangers to patient health were not performed, including tests for contaminants resulting from preparation or poor packaging.

Anabolic Steroids

Over a four-week period beginning October 18, 2004, NABP covertly monitored several eBay auctions and purchased four products that were purported to be anabolic steroids. All four products were shipped from different sellers located within the US without the requirement of a prescription. One product was unique because it was advertised on eBay as a "Book of Test Propionate Sustanon" with the explanation that it was a "10 chapter unopened book" of useful information on testosterone propionate 100 mg.

NABP worked with MSNBC to have all of the products sent to an independent laboratory for analysis. None of the four products contained exactly what was expected. Error attributable to analytical factors, such as extraction efficiency or yield, is most likely to blame for the inconsistency in three of the samples. It is likely that these three products are the actual pharmaceutical products they claim to be. However, the fourth sample, which claims to be Sustanon 250 by Organon, is potentially a counterfeit product because the differences between the expected and actual contents fall outside the normal error ranges.

As a result of NABP's investigation, eBay tightened its rules and its monitoring process to eliminate the illegal sales of steroids on its Web site.

Similare Drugs

In late 2004, NABP accepted a request from the pharmaceutical manufacturer, Eli Lilly, and FDA to evaluate Web sites that were allegedly selling prescription drugs that purported to be brand name medications or "similare" medications that claimed to be similar to or identical to their brand name counterparts, but, in fact, may have been subject to little or no testing or regulatory oversight. *Similares* are available in countries all over the world, particularly in Latin America, and are considered in many countries outside the US as legal and inexpensive

alternatives to patented drugs. Further, these *similares* are threatening to enter or may already have entered the US drug distribution system through the Internet and other sources.

NABP ordered several different medications including Cialis®, Evista®, and Zyprexa® from a total of 13 Web sites. No prescriptions were required by the sites. FDA performed an analysis of the submitted medications; two, in particular, were highly suspicious. Some of the sampled drugs far exceeded the level of allowed in the US medication. The amount of active ingredient present varied widely, and in at least one case, Fenilox (the "generic Evista"), no active ingredient was present. In addition, Lilly, the manufacturer of these drugs, performed a regulatory analysis on the products obtained by NABP and found that several were in fact *similares* and did not meet the company's US standards.

In May 2005, FDA issued a consumer advisory referencing the Evista that NABP purchased in addition to FDA's results from comparable tests on counterfeit versions of Lipitor® and Viagra® that were purchased in border towns of Mexico. Like the Evista *similare* in the NABP project, neither the counterfeit Lipitor nor the counterfeit Viagra contained any active ingredient.

NABP's findings of the availability of, and increasing occurrences of counterfeit drugs are troubling and concur with the findings of the FDA Task Force on Counterfeit Drugs.

VIPPS

Since 1999, NABP has successfully operated the Verified Internet Pharmacy Practice Sites™ (VIPPS®) accreditation program. VIPPS was developed in response to public concern about the safety of pharmacy practices on the Internet. A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria which VIPPS-accredited pharmacies follow.

To be VIPPS accredited, a pharmacy must comply with the licensing and inspection requirements of its home state and each state to which it dispenses prescription drugs. In addition, pharmacies displaying the VIPPS seal have successfully completed the VIPPS licensure verification process, an on-site inspection, and have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance practices, and provision of meaningful consultation between patients and pharmacists.

NABP'S RESPONSE TO THE FDA'S TASK FORCE ON COUNTERFEIT DRUGS

The FDA is to be commended for its excellent report and efforts to combat counterfeit drugs. NABP strongly supports the recommendations of the FDA Task Force and is collaborating closely with FDA Officials to implement the Task Force's recommendations.

Specifically, NABP has revised its Model Rules for the Licensure of Wholesale Distributors (Attachment A) to assist states in revising requirements for state licensure and regulation of wholesale distributors, created and maintains a National Specified List of Susceptible Drug Products (Attachment B), has made operational its Verified-Accredited Wholesale Distributors (VAWD) program to provide states with the resources to combat counterfeit drugs and adopt a national standard for the regulation of wholesale distributors engaged in intra and interstate commerce, and established uniform data field elements for electronic pedigrees (Attachment C). Each of these efforts coincides with recommendations from the FDA Task Force report and involves significant interaction and cooperation with the FDA and industry stakeholders.

NABP's VAWD Program

The Verified-Accredited Wholesale Distributors™ (VAWD™) program provides assurance that the wholesale distribution facility operates legitimately, is validly licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, an inspection, background checks, and screening through NABP's Clearinghouse. NABP has established and will operate and administer inspection services for the VAWD program. Inspections and inspectors will be managed and contracted directly through NABP.

VAWD was established in 2004 to help protect the public from the threat of counterfeit drugs affecting the US drug supply. NABP began developing VAWD after FDA requested that the Association update its Model Rules for the Licensure of Wholesale Distributors, which is part of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. Members of NABP's resulting Task Force on Counterfeit Drugs and Wholesale Distributors, held in October 2003, revised the Model Rules and proposed the creation of an accreditation program and clearinghouse for wholesale distributors – a plan that was immediately supported by FDA – to further combat counterfeit drugs.

The Model Rules for Licensure of Wholesale Distributors are just now being adopted by the states and NABP will take this into consideration as it evaluates applicants' documents and operations for purposes of VAWD accreditation. Bearing this in mind, provisional VAWD accreditation may be awarded to qualifying wholesale distributors. Throughout the creation of VAWD, NABP involved key stakeholders such as wholesale distributors, state boards of pharmacy, and other state and federal regulators to ensure that the program addresses the concerns of all interested parties.

CONCLUSIONS

NABP and the state boards of pharmacy consider the problem of counterfeit drugs a significant concern that must be addressed immediately and effectively. The present regulatory safeguards, which have been changed and strengthened in response to the FDA's Report on Counterfeit Drugs, require additional resources and support from state and federal legislatures to ensure that the US medication distribution system is not compromised. Adoption of NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program, Model Rules for the Licensure of Wholesale Distributors and the Verified-Accredited Wholesale Distributors (VAWD) programs are necessary to provide uniformity across the states and to ensure that "safe-havens" are not created for those entities that will seek to avoid regulation and operate illegally.

The cooperation among the states and the FDA is also critical to the success of any effort to maintain the integrity and security of the US medication distribution system. The collaborations between the FDA, NABP, and the state boards of pharmacy to combat the threat of counterfeit drugs have been exemplary and continue to grow as new challenges are faced and new strategies developed. If state and federal regulatory agencies are supported by Congress in these efforts through increased resources and legislation, the efforts to maintain the integrity and security of the US medication distribution system will be successful. If however, the illegal importation of drugs is encouraged and not halted and the US medication distribution system opened to the vagaries and dangers of an international counterfeit and diversion network that has already compromised the medication distribution systems of other countries, then little can be done to protect US citizens from peril.

Thank you for the opportunity to present this information to the Subcommittee.